Biotech Daily

Friday October 11, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.91 percent on Friday October 11, 2019, with the ASX200 up 59.7 points to 6,606.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell and six traded unchanged.

Oncosil was the best, up 1.1 cents or 16.9 percent to 7.6 cents, with 7.7 million shares traded. Neuren and Orthocell climbed more than eight percent; Optiscan was up 6.8 percent; Patrys improved five percent; Resonance and Uscom were up four percent or more; CSL and Genetic Signatures rose two percent or more; Amplia, Compumedics, Nanosonics and Next Science were up more than one percent; with Cochlear, Polynovo and Telix up by less than one percent.

Alterity (Prana) led the falls, down 0.5 cents or 15.15 percent to 2.8 cents, with 160,000 shares traded. Clinuvel, Dimerix and Kazia fell more than four percent; Antisense, Immutep and Opthea lost more than three percent; Actinogen, Impedimed and Universal Biosensors shed more than two percent; with Cynata, Mesoblast, Prescient, Pro Medicus, Proteomics, Resmed and Volpara down one percent or more.

DR BOREHAM'S CRUCIBLE: RECCE PHARMACEUTICALS

By TIM BOREHAM

ASX code: RCE

Share price: 27.5 cents

Shares on issue: 107,129,919*****

Market cap: $29.5 million; (*$36.6 million post-raising)

Chief executive officer (executive director): James Graham

Board: Dr John Prendergast (chairman), Dr Graham Melrose (chief research officer), Michele Dilizia, James Graham, Dr Justin Ward

Financials (year to June 30 2019): revenue nil, loss of $2.8 million (previously $1.7 million deficit), cash of $403,384 (previously $679,719)*****

***** Shares on issue and cash on hand are ahead of this week's placement of 26,032,478 shares that raised $6.76 million.

Major identifiable holders: Dr Graham and Olga Melrose 28%, Vesty Superannuation 4.3%, James Graham 4%, Foord Asset Management 3.9%.

If there's one reason to fear going into hospital a bit off color and emerging seriously ill, it's the strains of superbugs causing havoc in our healing institutions.

Pumping patients with traditional antibiotics isn't working, because the microscopic blighters have a habit of morphing and developing resistance.

Locally, the problem has been recognized by the Australian Pharmaceutical Benefits Advisory Committee, which this month recommended that repeat antibiotic prescriptions be banned.

Federal Health Minister Greg Hunt is pondering the proposal.

Recce itself is tackling sepsis, a life-threatening inflammation that spreads through the body via the blood as a result of infection.

Sepsis is frequently caused by bacteria including Staphylococcus aureus (Golden Staph) and Escherichia coli (E coli) but can also be caused by fungi and viruses.

Recce's great white hope is a synthetic broad-spectrum antibiotic called Recce-327, which has so far proved promising in animal testing.

To further the cause, the company has just raised $6.76 million in a placement.

A problem that really bugs us

The sobering stats show that sepsis is a leading cause of death in intensive care units and rates in the top 10 hospital mortalities globally.

The bug accounts for two percent of hospitalizations and 17 percent of hospital deaths, which just goes to show that hospitals are a dangerous place to be.

Someone in the world dies from sepsis every two minutes, while in the US it accounts for 270,000 deaths a year and costs the health system $US24 billion ($35 billion) a year.

Recce executive director James Graham notes the company has had positive results with seven of the 12 of the world's deadliest bacterial diseases, with the remaining five simply too dangerous to test.

"We aim to be the first approved drug for sepsis as a lead indication, given the unmet clinical need," he says.

Mr Graham says Recce's circumstances have changed from spruiking its message to being actively courted by hospitals and regulators (the former seeking compassionate use arrangements).

In November, chairman Dr John Prendergast will deliver the opening research and development address at the World Antimicrobial Resistance Congress, to be held in Washington on November 7.

Naturally, the jamboree features the who's who of the anti-infectives space.

"They are looking for what's next," Mr Graham says.

"There hasn't been a new class of antibiotic for over 30 years and the drug maker's pipelines are not providing the innovation the space needs."

The reason for this is that antibiotics are cheap and generic and not worth the bother, although amoxicillin (brand name Amoxin) is still a $US10 billion a year global drug.

Doing a 'recce' on Recce

Recce was co-invented by the company's founders, Dr Graham Melrose and Michele Dilizia, a medical scientist, former journalist - and Dr Melrose's daughter.

Recce was incorporated in 2007 and listed in January 2016, having raised $5 million by issuing 25 million shares at 20 cents apiece.

Dr Melrose was executive director and chief research officer at Johnson & Johnson's Australian arm.

Dr Melrose also headed the listed Chemeq, a veterinary drug outfit that was a market darling before collapsing in 2007 after alleged breaches of continuous disclosure requirements.

Dr Melrose had departed the company by then.

Chemeq was tackling E coli infections in pigs and chickens, albeit using completely different technology.

With a degree in entrepreneurship, Mr Graham invested in Recce in 2013 before joining the company in 2015. James Graham is Dr Graham Melrose's grandson.

Last year Recce changed its name from Recce to the more descriptive Recce Pharmaceuticals.

The lowdown on Recce-327

Recce-327 works on a unique mechanism of action involving hydrophonic interaction with the offending cells.

The antibiotic travels through the blood and is attracted to a protein in the bacteria's outer membrane. This weakens the cell wall, causing the germs to burst (cell lysis).

The binding properties of Recce-327 mean that it is more effective in tackling superbugs and it is effective on both Gram negative and Gram positive bacteria (the bugs fall into these two classes, as determined by the structure of the cell walls).

Recce-327 is classed as a qualified infectious disease product (QIDP) by the US Food and Drug Administration, under the US Generating Antibiotic Incentives (GAIN) Act.

This designation is for what the FDA believes to be "serious life-threatening infections caused by an antibacterial or antifungal resistant pathogen".

The QIDP status provides for 10 years' exclusivity post-approval and also fast-track approval of any developed drug.

Recce-327, by the way, is manufactured at Recce's Macquarie Park facility in Sydney, using cheap and abundant raw materials.

The ingredients? Bog-standard polyethylene glycol, acrolein (a derivative of the common gas propene) and water (a non-patented amalgam of hydrogen and oxygen molecules).

It works on mice (and rats, rabbits and dogs).

Recce's key selling point is that Recce-327 does not lose its efficacy after 25 or more doses. In comparison, with E coli infections the standard antibiotics can only be used twice before resistance sets in.

Recce so far has carried out more than 30 in-vitro and in-vivo studies on mice, rats, rabbits and dogs, with the data used to support the push for QIDP status.

The company is now girding for a phase I study on healthy individuals, structured in the typical way of single and ascending doses.

Royal North Shore Hospital spinal injury physician Dr David Bowers heads the company's clinical advisory committee.

In February, Recce submitted expanded preclinical data to the FDA, in view of gaining assent for a phase I human trial.

Structured as a single ascending and multiple ascending dosing regime, the mooted trial will target enrolment of 44 healthy adult patients.

The trial would be randomized, double blinded and placebo-controlled. And because it's easy to tell whether the drug works or not, data should be available within months of starting the study.

In pre-clinical work, a curative trial of 30 mice infected with methicillin-resistant Staphylococcus aureus (MRSA) showed all 10 in the Recce-327 cohort survived, and nine in the current-use MRSA antibiotic (oxacillin) survived. Of the 10 not treated, four hardy critters survived.

A preventative study showed that in all treated rodents, the bugs cleared naturally from the blood after 12 hours. With the untreated cohort, the bacteria rapidly colonized in the kidneys, which "commonly results in catastrophic organ failure".

While sepsis is top of Recce's germ-busting agenda, the company is also eyeing the production animal market (E coli), antiseptics for hospitals, households and travellers and preservatives (cosmetics, toiletries and pharmaceuticals).

In a win for promiscuous rodents, early mice trials suggested the compound was effective against gonorrhoea (as well as tuberculosis).

"We have a lot of opportunities to broaden our product range," Mr Graham says.

Finances and performance

Before this week's capital raising Recce had been living a hand-to-mouth existence, as highlighted by the "material uncertainty" statements in the accounts.

As of June 30, the company had cash of $400,000, having derived no revenue in the 2018-'19 year and incurred a $1.67 million loss.

Recce has used various mechanisms to keep the cash trickling in, including third-party arrangements to release expected Federal Research and Development Tax Incentive payments for working capital.

In February the company raised $1.8 million in a placement at 14 cents a share to its supportive chums.

It then raised $350,000 from local investors, repayable within six weeks or a capital raising "whatever is earliest".

This week's raising was struck at 26 cents a share, a 17.5 per cent discount to the prevailing price ahead of a trading halt on October 7.

Happy days! Mind you, Mr Graham sees joy in penury because the tight funding position has instilled management with a disciplined approach to spending.

"Some people would say 'you poor thing' but I'm quite proud of living on an oily rag."

Valuation wise, Recce has graduated from poverty corner: its shares climbed from a 12-month low of 14 cents in late February to a peak of 38 cents on September 23. The stock hit a record 46 cents in January 2016.

Dr Boreham's diagnosis:

It's still early days for Recce, but the company is tackling an urgent medical problem and has posted encouraging results to date.

While investors are latching on to the story like Recce-327 to a recalcitrant bug, global deals suggest that Recce could - or should - be worth more than its current sub $40 million valuation.

This year French group Deinove entered a licencing deal with Britain's Redx Pharma, which is all about whomping gram-negative bacteria.

Merck did likewise with the private Prokaryotics, which specializes in bacterial cell envelope enzymes.

In October 2017, Roche paid a heady $US387 million for Warp Drive Bio, a device company centred on detecting natural antibiotics.

Having got some much-needed dough through the door, Recce is one step closer to becoming the Mortein of the superbug world.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is bugged by many things, but thankfully not sepsis, golden staph or E coli.

OPTHEA

Opthea says OPT-302 with ranibizumab or Lucentis for wet age-related macular degeneration is specifically useful for choroidal neo-vascularization and lesions.
In August, Opthea said its 366-patient phase IIb trial of OPT-302 for wet age-related macular degeneration (AMD) showed the combination was statistically significantly superior to ranibizumab alone (BD: Aug 7, 2019).
Today, the company said further data supported the superiority of OPT-302 combination therapy over ranibizumab alone for treatment-naïve patients with choroidal neo-vascularization (CNV) secondary to wet AMD and wet AMD lesions of varying CNV classifications, including those with more difficult to treat morphology.
Opthea said it assessed the effects of OPT-302 combination therapy compared to ranibizumab alone in groups of patients with different choroidal neo-vascularization lesion types, including 44 percent minimally classic lesion types, 44 percent occult lesion types and 12 percent predominantly classic lesion types.
The company said that mean changes in best corrected visual acuity (BCVA) from baseline to week 24 when treated with OPT-302 combination therapy was 13.5 letters, compared to 6.9 letters in the ranibizumab control group.
Opthea chief executive officer Dr Megan Baldwin said that “achieving the primary endpoint of superior visual acuity gains in the phase IIb wet AMD study has highlighted the commercial potential of OPT-302 combination therapy, particularly given that improved efficacy is a major unmet need in retinal vascular disease”.
“These pre-specified sub-group and exploratory data analyses not only provide insight into which patients may be more likely to respond but also suggest improved benefit of OPT-302 combination therapy over anti-VEGF-A standard of care in difficult to treat retinal lesion types,” Dr Baldwin said.
Opthea fell 12 cents or 3.5 percent to $3.33 with 386,212 shares traded.

TRUSCREEN (FORMERLY POLARTECHNICS)

Auckland’s Truscreen says the World Health Organisation strategy to eliminate cervical cancer could provide a market opportunity for its screening technology.
In March, Truscreen chief executive officer Martin Dillon said the improved version of its cervical cancer test could be a primary screening tool (BD: Mar 19, 2019).
Mr Dillon said the technology worked by emitting light and an electric current to stimulate the cervix which “creates a tissue signature and reports whether it is normal or abnormal”.
Today, the company said the World Health Organisation strategy document called for a comprehensive global approach to screen, vaccinate and treat cervical cancer in combination and proposed a target of 70 percent of women between 35 and 45 years of age in WHO member countries to be screened with a high-precision test by 2030.
The company said the Organisation noted that it needed to adopt innovative and optimal service delivery models, particularly in low-and middle-income countries where cervical cancer incidence and mortality rates were high.
Truscreen said that a Chinese Obstetrics and Gynaecology Association independent 20,000-patient trial produced positive interim results for its Truscreen technology.
The company said the Zimbabwe National AIDS Council selected Truscreen to screen for HIV-affected women, due to the increased prevalence of cervical cancer among women with HIV/AIDS and it had facilitated a meeting between Unitaid and the National Institute of Cancer in Mexico to develop Mexico’s cervical cancer screening strategy, with a 1,000-patient pilot program approved by the Vietnam Ministry of Health.
On the NZX, Truscreen was unchanged at 11 NZ cents (10.3 Australian cents).

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has granted orphan status for its compound NNZ-2591 for Angelman syndrome.
Neuren said orphan drug designation would provide it a waiver of the prescription drug user fee for a marketing application and would qualify the sponsor of the drug marketing exclusivity for seven years, plus six months if approved for paediatric use.
Neuren executive chairman Dr Richard Treagus said the company had applied to the FDA for orphan status for Phelan-McDiarmid syndrome and Pitt Hopkins syndrome.
Neuren was up 19 cents or 8.9 percent to $2.33 with 601,518 shares traded.

ONCOSIL MEDICAL

Oncosil says it has US Food and Drug Administration humanitarian use designation and is making progress on its Conformité Européene (CE) mark application.
Oncosil said the FDA granted its radiation treatment humanitarian use designation (HUD) for intra-hepatic cancer and distal cholangiocarcinoma, or bile duct cancer.
The company said it would apply to the FDA for a humanitarian device exemption, using data from its Brachysil radiation for pancreatic cancer or Panco study.
Oncosil chief executive officer Daniel Kenny said that humanitarian use designation was "a significant milestone for the company and creates a pathway for US approval for our device to treat a malignancy for which very few treatment options are available".
Oncosil said the British Standards Institute and the Clinical Oversight Committee had requested a clinical evaluation report including study data for its CE mark application.
"Submitting the CER as quickly as possible remains our immediate focus and we expect to submit in the coming weeks," Mr Kenny said.
Oncosil was up 1.1 cents or 16.9 percent to 7.6 cents with 7.7 million shares traded.

OVENTUS MEDICAL

Oventus says it has launched the first five 'lab-in-lab' sites in the US and Canada to coincide with the launch of its O2Vent optima oral device for obstructive sleep apnoea.
Last month, Oventus said it had US Food and Drug Administration clearance for its O2Vent Optima, which was part of its sleep treatment platform and laboratory inside a laboratory or 'lab in lab' business model, which used "a scanner to measure the patient's mouth size for a custom-fit for the O2vent" (BD: Sep 2, 2019).
Today, the company said it had officially launched a wide-scale digital marketing and outreach campaign and would target sleep and dental channels.
Oventus fell four cents or 5.4 percent to 70 cents.

BLUECHIIP

Bluechiip says it had cash and cash equivalents of $2,801,000 at September 30 and expected a cash outflow of $2,677,000 for the three months to December 31, 2019.
Bluechiip said that the cash burn for the three months to September 30 was $1,072,000 with customer receipts for the three months of $441,000.
Bluechiip chief executive officer Andrew McLennan told Biotech Daily: We have sufficient cash and expected receipts, including more than $1 million from a Federal Research and Development Tax Incentive to keep us going for more than two quarters".
The company said receipts were from sales of its chips, readers, software and services.
Bluechiip was up half a cent or 3.3 percent to 15.5 cents with 2.7 million shares traded.

INVITROCUE

Invitrocue says the extraordinary general meeting resolution to remove chief executive officer Dr Steven (Boon Sing) Fang was lost by 42 million votes (12%).
Invitrocue said 286,562,135 votes (56.1%) were against the resolution and 224,428,768 votes (43.9%) were in favour.
Invitrocue's most recent Appendix 3B new issue announcement said it had 578,486,901 shares on issue meaning that the votes in favor of removing Dr Fang amounted to 38.8 percent of the total shares on issue, sufficient to requisition an extraordinary general meeting.
Invitrocue was in a suspension and last traded at six cents.

IMPEDIMED

Impedimed says it faces a remuneration report second strike, and investors will vote to grant chief executive officer stock and shares to directors in lieu of cash payments.
Impedimed said it would vote to grant chief executive officer Richard Carreon 1,992,612 options exercisable at the 5-day volume-weighted average price to the date of grant and 1,962,871 performance rights, pending performance targets.
The company said it would vote to grant Mr Carreon shares of up to 20 percent of his gross annual base salary or up to 20 percent of any short-term incentives.
Impedimed said it would vote to grant non-executive directors Scott Ward, Judith Downes, Don Williams, Armit Patel, Gary Goetzke and Dr Robert Graham shares in lieu of cash under its non-executive director share plan.
Impedimed said that if the vote on the remuneration report had 25 percent of the votes or more against, it would have a 'second strike' and had a provisional spill resolution.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.
If the spill vote fails, the trigger is reset to no opposition.
Last year, the company said 44.3 percent of votes opposed the remuneration report with more than 22 percent opposition to shares and options for Mr Carreon and the election of three directors (BD: Oct 17, 2018).
The company said it would vote to adopt its remuneration report, re-elect directors Mr Patel and Mr Williams, approve an additional 10 percent capacity to issue shares and amend its constitution to include a non-executive director share plan provision.
The meeting will be held at the offices of Johnson Winter & Slattery at Level 25, 20 Bond Street, Sydney on November 12, 2019 at 9am (AEDT).
Impedimed fell half a cent or 2.9 percent to 16.5 cents.

ANTISENSE THERAPEUTICS

Platinum Investment Management says it has reduced its substantial shareholding in Antisense from 31,755,652 shares (7.58%) to 26,335,114 shares (6.27%).
The Sydney-based Platinum said that between July 31 and October 9, 2019 it disposed of 5,420,538 shares for $389,620.73 or an average of 7.2 cents a share.
Antisense fell 0.3 cents or 3.1 percent to 9.4 cents with 3.3 million shares traded.

MEDADVISOR

HMS Holdings (Health Management Systems) says it has become a substantial shareholder in Medadvisor with 220,000,000 shares or 12.8 percent.
The Texas, United States-based HMS said that on October 11, 2019 it bought the shares for $11,000,000 or 5.0 cents a share.
On Monday, Medadvisor said it raised $17 million, with $11 million from HMS, with HMS chief financial officer Jeff Sherman to be appointed a director (BD: Oct 7, 2019)
Medadvisor was up 0.1 cents or 1.9 percent to 5.3 cents with 1.5 million shares traded.

ALCIDION GROUP

Alcidion director Raymond Blight says he has increased and been diluted in Alcidion from 100,264,121 shares (12.44%) to 100,578,081 shares (11.17%)
The Mount Osmond, South Australia-based Mr Blight said that on November 29, 2018 his spouse Robyn Morris bought 1,000,000 shares for $48,050 or 4.8 cents a share in an off-market trade and they were diluted in the exercise of 5,000,000 options at eight cents each by former director Brian Leedman (BD: Aug 27, 2019).
In August, Alcidion said 686,040 shares held indirectly by Mr Blight were sold by Ms Morris during a closed trading period for $120,000 or 17.5 cents a share, an unintentional breach (BD: Aug 29, 2019).
Alcidion was up 1.5 cents or 5.8 percent to 27.5 cents with 4.4 million shares traded.

DIMERIX

Dimerix says non-executive director David Franklyn will step down effective immediately.
Dimerix said the decision was “predicated on having taken on a new role that introduces a potential conflict of interest to his non-executive responsibilities”.
Dimerix fell half a cent or 4.35 percent to 11 cents with 1.2 million shares traded.